



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,472	07/02/2003	Frederick M. Ausubel	00786/254004	5312
21559	7590	05/04/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			KUBELIK, ANNE R	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,472	Applicant(s) AUSUBEL ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1638

DETAILED ACTION

1. The finality of the Office action mailed 21 October 2005 is withdrawn in favor the new rejections below.
2. Claims 8-10 and 12-14 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claim 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in light of Applicant's cancellation of the claim.
5. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Keen et al (1993, Biotechnology in Plant Disease Control (Chet, ed.), pg 65-88) is withdrawn in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 112

6. Claims 8-10 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

It is unclear in claim 8, step (c), what the practitioner of the method does to express the candidate gene and the reporter gene in the plant tissue sample. The claims do not indicate that the genes have inducible promoters, for example, which would require action by the practitioner, and dependent claim 10 even specifies a constitutive promoter, which would express the both the disease resistance and reporter coding sequence without action by the practitioner.

Art Unit: 1638

Claim 8 is indefinite in its recitation of “determining” in part (d), as this is a mental process and not an active, positive step.

Claim 8 is indefinite in its recitation of “plant disease resistance gene” and “reporter gene”. A gene consists of a coding region as well as all the 5’ and 3’ regulatory regions associated with it. However, dependent claims 10 and 13 suggest that Applicant intends other regulatory regions to be associated with plant disease resistance and reporter coding regions.

It is unclear in claim 14 if “differences in GUS activity are detected histochemically” somehow further limit “GUS” or if this is an additional method step. If the latter, it is unclear where this step occurs in the method.

Claim Rejections - 35 USC § 103

7. Claims 8-10 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes et al (1993, Plant Science 89:43-53) in view of Daniell et al (US Patent 5,693,507, filed at least January 1991). The rejection is modified from the rejection set forth in the Office action mailed 21 October 2005, as applied to claims 1-2. Applicant’s arguments filed 23 March 2006 have been fully considered but they are not persuasive.

The claims are drawn to a method of identifying plant disease resistance genes comprising introducing a candidate gene and a reporter gene into a plant via biolistic transformation and assaying the plant for disease resistance.

Jaynes et al disclose a method of identifying genes that confer disease resistance on a plant, wherein the method comprises introducing a candidate gene encoding cecropin B and a

Art Unit: 1638

reporter gene, the kanamycin resistance gene, under the control of 35S or an inducible promoter into a tobacco plant via Agrobacterium transformation and assaying the plant for disease resistance (pg 45, right column, to pg 46, left column, and 48-50). The initial plant used for transformation would contain a null mutation of the disease resistance gene. Jaynes et al do not disclose use of biolistic transformation in the method.

Daniell et al teach biolistic transformation of tobacco (column 11, lines 55-65)

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of identifying genes that confer disease resistance as taught by Jaynes et al, to introduce the gene via biolistic transformation as described in Daniell et al. One of ordinary skill in the art would have been motivated to do so because selection of one transformation method over another is an obvious design choice.

Applicant urges that claims 1-2 have been cancelled (response pg 5).

This is not found persuasive because the rejection is now applied to claims 8-10 and 13 as detailed above.

8. Claims 8-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et al (1993, Biotechnology in Plant Disease Control (Chet, ed.), pg 65-88). The rejection is modified from the rejection set forth in the Office action mailed 21 October 2005, as applied to claims 1-7 and 11. Applicant's arguments filed 23 March 2006 have been fully considered but they are not persuasive.

Art Unit: 1638

The claims are drawn to a method of identifying plant disease resistance genes comprising introducing a candidate gene and a reporter gene into a plant via biolistic transformation and assaying the plant for disease resistance.

Keen et al disclose a method of identifying plant disease resistance genes comprising introducing candidate genes from cDNA libraries operably linked to the 35S promoter into a plant via biolistic transformation and assaying the plant for disease resistance (pg 79, paragraph 4, to pg 82, paragraph 1). The plant would comprise leaves, roots and stems and at certain points in its life would comprise flowers and fruit. The assayed disease resistance response is the hypersensitive response (pg 80, paragraph 1; pg 81, paragraph 2). Keen uses plant lines lacking the resistance gene; these lines would have null mutant genes (pg 79, paragraph 4). Keen uses plant tissues including hypocotyls as the plant source (pg 80, paragraph 3)

Keen does not disclose using a reporter gene.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of identifying plant disease resistance genes as taught by Keen, to co-transform a “reporter gene” like an antibiotic resistance gene into a plant. One of ordinary skill in the art would have been motivated to do so because co-transformation of the gene of interest with a selectable “reporter gene” is the common way plant transformation is performed; expression of the selectable “reporter gene” allows elimination of nontransformed plants or plant cells.

Applicant urges that claims 1-7 and 11 have been cancelled (response pg 6).

Art Unit: 1638

This is not found persuasive because the rejection is now applied to claims 8-10 and 13 as detailed above.

9. Claims 12 and 14 are free of the prior art, given the failure of the prior art to teach or suggest a method of identifying plant disease resistance genes comprising introducing a candidate genes and a GUS gene into a plant via biolistic transformation and assaying the plant for disease resistance.

10. Claims 12 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

Art Unit: 1638

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.

April 19, 2006



**ANNE KUBELIK, PH.D.
PRIMARY EXAMINER**